DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 23, 2015

GN Otometrics A/S
% Mr. Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K143670
Trade/Device Name: ICS Chartr EP 200 with VEMP
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: September 22, 2015
Received: September 25, 2015

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclose

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143670

Device Name
ICS Chartr EP 200 with VEMP

Indications for Use *(Describe)*
The ICS Chartr EP 200 with VEMP is indicated for auditory evoked potential testing as an aid in assessing hearing loss and lesions in the auditory pathway. The Vestibular Evoked Myogenic Potential is indicated for vestibular evoked potential testing as an aid in assessing vestibular function in adult patients. The device is to be used only by qualified medical personnel with prior knowledge of the medical and scientific facts underlying the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary, 510(k) K143670

Submitter: GN Otometrics A/S
Hoerskaetten 9
Taastrup, DENMARK DK-2630
Registration number: 9612197
(US) Phone: 847-534-2150
Contact: Anders Rasmussen
arasmussen@gnotometrics.com
Date Prepared: October 14, 2015

1. Identification of the Device:
Proprietary-Trade Name: Chartr EP 200 with VEMP
Classification Name: Stimulator, Auditory, Evoked Response
Common/Usual Name: Auditory Evoked Response Stimulator.
Product code: GWJ
Classification Panel: Neurology
Device Class: Class II
FDA CFR Section: 21CFR 882.1900

2. Equivalent legally marketed devices: **Chartr EP200, K092373, GN Otometrics**

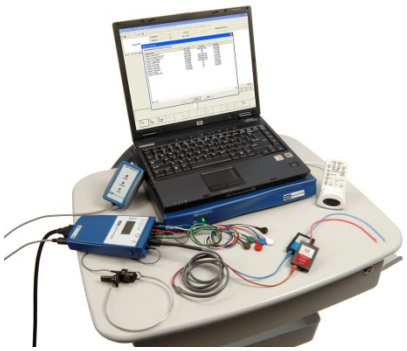
3. Description of the Device: "Vestibular Evoked Myogenic Potentials (VEMPs) are short latency electromyograms (EMGs) evoked by high level acoustic stimuli recorded from surface electrodes over the tonically contracted sternocleidomastoid (SCM) muscle." Akin FW & Murnane OD (2001).

The ICS Chartr EP 200 with VEMP is used to test the auditory and vestibular functions of children and adults in a hospital, in an Ear, Nose and Throat Clinic or in an Audiology office. The ICS Chartr EP 200 system measures evoked potentials from the patient using repeated auditory stimuli and averaging EEG or EMG activity in order to abstract the response from the noise resulting in an analysis of the auditory/vestibular system functions.
The ICS Chartr EP 200 is a PC-based system, which consists of software modules for installation on a PC, an isolation transformer, a hardware platform, pre-amp, a mains adapter, stimulation devices and recording devices. The stimulation and recording devices are connected to the pre-amp, which is connected to the hardware platform, which is connected to the PC via a USB cable – no hardware installation inside the PC is required. The PC and hardware platform are powered from the isolation transformer which is powered from the mains.
One added item as compared to the standard EP200 is the VEMP monitor. The Chartr EP (USB) VEMP monitor assesses the level of tonic EMG and displays if the level is adequate or inadequate. The monitor light will display the following based on the EMG level: Low (blue) - EMG level is below the Min value- Good (green) - EMG level is between Min value and the Max value - High (amber) - EMG level is above the Max value
Summary: VEMP is an evoked potential (EP) just like ABR obtained using any commercially available EP system. The unique feature with the ICS Chartr EP 200 is the ability to perform EMG monitoring during VEMP data collection.
The VEMP function of the EP 200 does not make a diagnosis. The diagnosis is made by a medical professional.

4. **Indications for Use**: The ICS Chartr EP 200 with VEMP is indicated for auditory evoked potential testing as an aid in assessing hearing loss and lesions in the auditory pathway. The Vestibular Evoked Myogenic Potential is indicated for vestibular evoked potential testing as an aid in assessing vestibular function in adult patients. The device is to be used only by qualified medical personnel with prior knowledge of the medical and scientific facts underlying the procedure.

5. **Safety and Effectiveness, comparison to predicate device**. The ICS Chartr EP 200 with VEMP is uses the same construction as the predicate K092373 and adds VEMP required software and hardware, i.e. a VEMP monitor channel.

6. Substantial Equivalence Chart

	Chartr EP200, K092373, GN Otometrics	Chartr EP200 with VEMP, GN Otometrics, K143670
Indications for Use:	The ICS Chartr EP 200 System is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.	The ICS Chartr EP 200 with VEMP is indicated for auditory evoked potential testing as an aid in assessing hearing loss and lesions in the auditory pathway. The Vestibular Evoked Myogenic Potential is indicated for vestibular evoked potential testing as an aid in assessing vestibular function in adult patients. The device is to be used only by qualified medical personnel with prior knowledge of the medical and scientific facts underlying the procedure.
Configuration	PC-based system with external hardware platform and external hardware peripherals (USB interface)	SAME
Photo	 (The appearance of the equipment has not changed)	
Hardware Implementation	PC-based system with external hardware platform and peripherals (USB interface)	SAME
Tests Performed	Electrocochleography (ECochG) Auditory Middle Latency Response (AMLR) Auditory Late Response (ALR) P300 - optional	Electrocochleography (ECochG) Auditory Middle Latency Response (AMLR) Auditory Late Response (ALR) P300 - optional Auditory Steady State Response (ASSR) – optional

	Chartr EP200, K092373, GN Otometrics	Chartr EP200 with VEMP, GN Otometrics, K143670
	Auditory Steady State Response (ASSR) – optional	New: Vestibular Evoked Myogenic Potential (VEMP) – optional
Size	Chartr EP 200 main unit: 4.9cm x 34.2cm x 28.7cm (2" x 13.6" x 11.3") – 2.7kg (5 lbs 7oz) Chartr EP 200 Preamp: 3cm x 9.9cm x 16.4cm (1.19" x 3.88" x 6.44") – .27kg (9.5oz)	Chartr EP 200 main unit: 4.9cm x 34.2cm x 28.7cm (2" x 13.6" x 11.3") – 2.7kg (5 lbs 7oz) Chartr EP 200 Preamp: 3cm x 9.9cm x 16.4cm (1.19" x 3.88" x 6.44") – .27kg (9.5oz) Chartr VEMP Monitor: 2.9cm x 6.2cm x 9.5cm (1.13" x 2.44" x 3.75") – 2.0kg (4.5oz
VEMP Monitor	Not applicable	VEMP monitor (described above) 
Computer Operating System	Microsoft XP Professional - Service Pack 2 or Vista Business,	Windows 7, 32 or 64 bit Windows 8, 32 or 64 bit
Power	AC line	SAME
Isolation Transformer	POWERTRONIX Isolation Station	SAME
Display	Minimum screen resolution of 1024 (horiz) x 768 (vert) at 96 dpi. At Large size (120 dpi) setting, minimum resolution is 1280 (horiz) x 960 (vert) Display Color: 32 bit color.	SAME
Safety Standards	EN 60601-1 + A1 + A2; EN 60601-1-2	SAME

7. **Summary of non-clinical testing: (Performed in K092373):** Bench testing demonstrated compliance with system hardware and software specifications. There are no changes in electrical safety or EMC characteristics as compared to our predicate Chartr EP200. Software validation and risk analysis was performed to confirm the proper functions of the VEMP protocol.

8. **Summary of clinical testing:** VEMP is a well-documented and studied technique. Numerous clinical references are available using various equipment including our Chartr EP200. We presented clinical studies of the VEMP response using the EP200 in our submission. We also performed studies to confirm the reproducibility of the VEMP waveform. The reproducibility of the VEMP waveform is very similar to that of any other evoked potential waveform.
Summary the clinical data for our correlation study:
Studies were collected at two different facilities, one in the USA and one in Canada.
Subjects: Adults:

There are a total of 60 normal cVEMP subjects.
There are 58 pathologic (patients with disorders) .cVEMP subjects.
There are 20 oVEMP normal subjects
cVEMP normal group consisted of 29 males and 31 females.
oVEMP normal group consisted of 7 males and 13 females.
cVEMP pathologic group consisted of 27 males and 31 females.
Each facility uses the same test parameters:

Minimum number of runs per ear	2
Number of channels	2
Transducer	Insert phones
Gain	5,000
Stimulus	500 Hz tone burst (Blackman)
Rate	5.1
dbHL	90-95 dBHL
High Pass Filter	10 Hz
Low Pass Filter	1000 Hz

The correlation results were as follows:
For normal subjects cVEMP we calculated the following Correlation values:

CORR R (entire window)	0.893448276
CORR L (entire window)	0.903448276
5-35ms CORR R	0.914655172
5-35ms CORR L	0.916206897

For patients with disorders, we calculated the following Correlation values:

CORR R (entire window)	0.751964286
CORR L (entire window)	0.75637931
5-35ms CORR R	0.775172414
5-35ms CORR L	0.805

For normal oVEMP subjects we calculated the following Correlation values:

CORR R	0.897
CORR L	0.8915
4-20ms R	0.926
4-20ms L	0.93

There was a lower correlation value in the patients with disorders because many of these patients may have absent or abnormal cVEMPs (reduced, inconsistent, etc). This inevitably brings the correlation value down since there is no correlation (0.00%) when there is no response.
Conclusion: As with other evoked potential procedures, VEMP shows reproducibility which makes it useful to the clinician.

9. Conclusion: After analyzing bench testing, safety, EMC, software, and clinical validation testing we conclude that the Chartr EP200 with VEMP (the expanded indication for use) is as safe and effective as the predicate device, and has essentially the same technological characteristics, thus rendering it substantially equivalent to the predicate devices.